

REMARKS

Applicants respectfully request entry of the remarks submitted herein. Claims 1-3, 10, 11, 16, 19, 22, 25, 34, and 43 have been amended herein. The amendments serve to clarify the respective methods steps, and do not introduce new matter. Claims 36-42 have been canceled herein without prejudice. New claims 52-61 have been added herein. Support for new claims 52-61 can be found in the originally filed claims and throughout the specification. Therefore, claims 1-35 and 43-61 are currently pending. Reconsideration of the pending application is respectfully requested.

The 35 U.S.C. §112 Rejections

The Examiner indicated that claims 24-66 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicants regard as the invention. Applicants believe that claims 1-51 stand rejected under this section, and not claims 24-66. Applicants respectfully traverse this rejection with respect to claims 1-51.

The Examiner indicated that the “5% or less genetically modified” seed or crop material referred to in claims 1, 36, and 43, and the “less than 5% non-genetically modified” seed referred to in claim 22 must be accompanied by a probability level.

The test for definiteness, as stated by the Court of Appeals for the Federal Circuit, is “whether one skilled in the art would understand the bounds of the claim when read in light of the specification If the claims read in light of the specification reasonably apprise those skilled in the art of the scope of the invention, §112 demands no more” *Miles Laboratories, Inc. v. Shandon Inc.*, 997 F.2d 870, 27 USPQ2d 1123 (Fed. Cir. 1993), *cert. denied* 510 U.S. 1100 (1994). In the instant application, the specification reasonably apprises those skilled in the art of the scope of the invention, and the Examiner has not provided any reason as to why one skilled in the art would not understand the scope of the claims when read in light of the specification.

With respect to the Examiner's rejection, Applicants are unclear as to what a "probability level" is. Applicants cannot find a reference to "probability level" in a well-known statistics textbook, *Biostatistical Analysis* (2nd Ed., Zar, JH, Prentice-Hall, Inc., Englewood Cliffs, N.J., 1984). *Biostatistical Analysis* does refer to "probability of a test statistic", "probability of two events", and "probable error." Applicants respectfully request clarification from the Examiner as to the meaning of "probability level." In the meantime, Applicants assume that "probability level" refers to the "probability of a test statistic" (P), which is a measure of statistical significance (see pages 42-43 of *Biostatistical Analysis*, copy enclosed), and submit the following.

Grain handlers routinely describe grain by its quality. For example, grain quality can be evaluated by determining the presence and amounts, for example, of damaged grain, foreign matter, off-color grain, and mottled or stained grain indicative of an infection or other substances. The amounts of damaged grain, foreign matter, off-color grain, etc. are expressed as a percent, which is generally not accompanied by any other number (*e.g.*, a P -value, a standard error (SE), a standard deviation (SD), or a standard error of the mean (SEM)). Applicants respectfully refer the Examiner to the attached 'Official United States Standards for Grain, Subpart A—General Provisions' from the U.S. Department of Agriculture. Under the heading 'Principles Governing the Application of Standards', section (§) 810.104 addresses 'Percentages' and provides standards for rounding and recording percentages obtained from quality determinations of grains. Applicants also attach 'Subpart J—United States Standards for Soybeans,' which describes the specific grain standards for soybeans. Applicants respectfully refer the Examiner to page J-3, §810.1604, which describes 'Grades and grade requirements for soybeans' and shows a table of standards for different grades of soybeans. Applicants note that this table of soybean standards under the U.S. Grain Standards Act contains percent values without any type of "probability level."

The Federal Circuits' opinion in *Modine Mfg. Co. v. U.S. Int'l Trade Comm'n* (75 F.3d 1545, 37 USPQ2d 1609 (Fed. Cir. 1996), *cert. denied*, 518 U.S. 1005 (1996)) is in agreement with Applicants' arguments presented above with respect to the absence of probability levels used by those of skill in the art. In *Modine Mfg. Co. v. U.S. Int'l Trade Comm'n*, the court stated "[m]athematical precision should not be imposed for its own sake; a patentee has the right to

claim the invention in terms that would be understood by persons of skill in the field of the invention.”

Since those of skill in the art routinely refer to percentages in the absence of any type of “probability level,” the present claims are not indefinite. Therefore, Applicants respectfully request that the rejection of claims 1-35 and 43-61 under 35 U.S.C. §112 be withdrawn.

The 35 U.S.C. §103 Rejections

The Examiner rejected claims 1-3, 6-10, 13-21, 22-25, 28, 29, 30-33, 36-39 and 43-51 under 35 U.S.C. §103(a) as being unpatentable over Poehlman (document AEE from Applicant's 1449) in view of Reuters (*Chicago Sports Final Ed.*, page 4, 3 Sept. 1998). Applicants respectfully traverse this rejection.

In the current Office Action, the Examiner maintained the claim rejections from the February 1, 2002 Office Action and asserted essentially the same reasons.

Applicants resubmit the arguments submitted in the July 1, 2002 Response with respect to this rejection.

In explaining the rejection of these claims in both the February 1, 2002 and the present Office Action, the Examiner includes the language “and visually inspecting field for any crop plant growing and eliminating off-types whether they be genetically or nongenetically modified,” implying that the Poehlman reference teaches or discloses such a step. The Examiner refers to page 451, column 2, sections b and d when including this language. This section of the Poehlman reference discloses that seed must be planted on clean ground, and that off-types must be rogued out. This section of the Poehlman reference does not provide any disclosure on “genetically or nongenetically modified” crop plants or how to distinguish between the two. Thus, the Examiner is reading subject matter into the Poehlman reference that is not present. The Poehlman reference does not teach or disclose such language.

In response to Applicants' previously submitted arguments, the Examiner indicated that he considers the visual screening procedures disclosed in the Poehlman reference “to be adequate to distinguish between genotypes when they cause different phenotypes regardless of the seed being GMO or non-GMO.” The Examiner went on to say that he considers the Poehlman reference to disclose methods for keeping seed pure for both breeders and farmers. The

Examiner further stated that he considers GMO seed in non-GMO seed to be an off-type, and indicated that although the Poehlman reference predates the development of GMOs, the Poehlman reference is being used for its concept and methods of maintaining pure seed. The Examiner considered the combination of the Poehlman reference and the Reuters reference to be proper because the Poehlman reference discloses the concept and methods of maintaining pure seed and the Reuters reference discloses the need to guard against contamination by GMOs.

Applicants submit that the visual inspection disclosed in the Poehlman reference is not adequate for use in the present invention, because many GMO and non-GMO varieties are visually phenotypically identical. In addition, Applicants have addressed the differences between breeders and farmers, and have submitted a Declaration from Mr. Robert Peterson, in which Mr. Peterson states that the Poehlman reference does not disclose certification methods for seeds to be used in farming operations (Peterson Declaration #17 & 18). According to Article 14, Chapter 27 of the Seed Certification Standards for Clemson University (copy enclosed), "off-type" refers to a plant or seed that differs visibly in one or more characteristics from that which had been described by the breeder as being usual for the strain or variety. As Applicants stated above, many GMO and non-GMO varieties are visually phenotypically identical. Therefore, and contrary to the Examiner's statement, GMO seed in non-GMO seed generally would not be considered by those of ordinary skill in the art to be an off-type.

In addition, the Examiner stated that the phrase "offers useful service by encouraging the general use of pure seed of improved varieties throughout the state" from the Poehlman reference can include farming activities such as keeping equipment and storage facilities clean, planting and harvesting pure seed, and actively maintaining pure seed. The Examiner is reading additional subject matter into the Poehlman reference as is apparent from the Declaration of Mr. Peterson.

Applicants submit that neither the Poehlman reference nor the Reuters reference can address the complexities involved in farming and processing GMO-free non-GMO crops. The Examiner is using hindsight in combination with nonanalogous art to arrive at the claimed invention. Accordingly, Applicants respectfully request that the rejection of claims 1-3, 6-10, 13-21, 22-25, 28, 29, 30-33, and 43-51 under 35 U.S.C. §103 be withdrawn.

The Examiner rejected claims 4, 5, 26 and 27 under 35 U.S.C. §103(a) as being unpatentable over Poehlman (document AEE from Applicant's 1449) in view of Reuters (Chicago Sports Final Ed., page 4, 3 Sept. 1998) in further view of *Use of DNA in Identification* ("Lander", document AU from Applicant's 1449). This rejection is respectfully traversed.

The Examiner maintained the claim rejections from the February 1, 2002 Office Action in the current Office Action, and asserted essentially the same reasons.

Applicants resubmit the arguments submitted in the July 1, 2002 Response.

In response to Applicants' arguments, the Examiner indicated that the combination of the Poehlman reference and the Reuters reference with the Lander reference is proper because the Lander reference discloses a method of separating phenotypes by comparing genotypes with DNA fingerprinting. The Examiner indicated that the goal in the Lander reference is, in essence, the same goal as that in the Poehlman and Reuters references achieved by different means.

Applicants have indicated in the July 1, 2002 Response why the Poehlman reference and the Reuters reference do not make the claimed invention obvious. The Lander reference does not cure the deficiencies of the Poehlman and Reuters references. None of the cited references, either alone or in combination, provide a reasonable expectation of success of applying the claimed invention to prepare a non-genetically modified processed food product (claims 4 and 5), or to minimize contamination of genetically-modified processed grain (claims 26 and 27). Accordingly, Applicants respectfully request that the rejection of claims 4, 5, 26 and 27 under 35 U.S.C. §112 be withdrawn.

The Examiner rejected claims 11, 12, 34 and 35 under 35 U.S.C. §103(a) as being unpatentable over Poehlman (document AEE) in view of Reuters (Chicago Sports Final Ed., page 4, 3 Sept. 1998) in further view of Montanari et al. (U.S. Patent No. 5,478,990; document AD from Applicant's 1449). Applicants respectfully traverse this rejection.

The Examiner maintained the claim rejections from the February 1, 2002 Office Action in the current Office Action, and asserted essentially the same reasons.

Applicant's resubmit that arguments submitted in the July 1, 2002 Response.

In view of Applicants' arguments, the Examiner indicates that although the ID tracking system in the Montanari reference is used in animals, the goal is compatible with the goal of the

Poehlman reference, that being to maintain pure seed. The Examiner considered it "proper to combine the concept and methods of maintaining pure seed lots with the concept and method to ensuring [*sic*] the documented history of products."

With respect to the combination of the Poehlman reference, the Reuters reference, and the Montanari reference, there is simply no motivation to combine the references and arrive at the claimed invention. Given that the Montanari reference discloses tracking animals from origin to processing, the Montanari reference certainly cannot provide the motivation to combine the cited references to prepare a non-genetically modified processed food product (claim 1), or to minimize contamination of genetically-modified processed grain (claim 22). Such motivation also is not present in the Poehlman or the Reuters reference. Moreover, even if the goals of the cited references are considered compatible, a reference that discusses animals cannot possibly provide any sort of reasonable expectation of success with plants. Accordingly, Applicants respectfully request that the rejection of claims 11, 12, 34 and 35 under 35 U.S.C. §103 be withdrawn.

CONCLUSION

Applicants ask that all claims 1-35 and 43-61 be allowed. Enclosed is a check in the amount of \$232 (\$205 for Two-Month Petition for Extension of Time and \$27 for additional claims). Please apply any other charges or credits to Deposit Account No. 06-1050.

Respectfully submitted,

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the Claims:

Claims 36-42 have been canceled.

Claims 1-3, 10, 11, 16, 19, 22, 25, 34, and 43 have been amended as follows:

1. (Amended) A method for preparing a non-genetically modified processed food product, comprising:
 - a) certifying that a crop was grown and harvested [non-genetically modified seeds were grown] under conditions effective for said crop to contain [harvesting a crop containing] 5% or less genetically modified seeds; and
 - b) certifying that said crop was processed under conditions effective for [producing] said processed food product[, said food product containing] to contain 5% or less genetically modified crop material.
2. (Amended) The method of claim 1, wherein said conditions in said certifying step a) are effective for [producing a] said crop to contain [containing] 0.01% or less genetically modified seeds.
3. (Amended) The method of claim 1, wherein said conditions in said certifying step b) are effective for [producing a] said processed food product to contain [containing] 0.01% or less genetically modified crop material.
10. (Amended) The method of claim 1, wherein said certifying step b) comprises:
 - i) inspecting for contamination by genetically modified seeds, prior to [said] harvesting said crop [step], one or more storage bins for said crop; and
 - ii) inspecting for contamination by genetically modified seeds, prior to producing said processed food product [processing step], one or more processing plants that are to process said crop.
11. (Amended) The method of claim 1, wherein said certifying step b) comprises establishing a lot identification number for said crop prior to producing said processed food product [processing step] and tracking said lot identification number during said processing [step].

16. (Amended) The method of claim 15, wherein said conditions in said certifying step a) and said conditions in said certifying step b) are effective for [producing a] said processed food product to contain [containing] 0.1% or less genetically modified crop material.

19. (Amended) The method of claim 18, wherein said conditions in said certifying step a) and said conditions in said certifying step b) are effective for [producing a] said processed food product to contain [containing] 0.01% or less genetically modified crop material.

22. (Amended) A method for minimizing contamination of genetically modified processed grain, comprising:

a) certifying that a harvested genetically modified crop contains less than 5% non-genetically modified seeds; and

b) certifying that said crop was processed under conditions effective for [producing] said genetically modified processed grain to contain [containing] less than 5% non-genetically modified seeds.

25. (Amended) The method of claim 22, wherein said conditions in said certifying step b) are effective for [producing] said processed grain to contain [containing] 0.01% or less non-genetically modified seeds.

34. (Amended) The method of claim 22, wherein said certifying step b) comprises establishing a lot identification number for said crop prior to said processing[step].

43. (Amended) A method for minimizing contamination of a non-genetically modified processed food product, comprising:

a) inspecting [for contamination by genetically modified crop material] a processing facility that is to process a harvested crop for contamination by genetically modified crop material, wherein said inspecting is performed prior to processing said harvested crop;

b) testing said harvested crop for contamination by genetically modified crop material, wherein said testing is performed prior to processing of said harvested crop by said processing facility to make said non-genetically modified processed food product; and

c) certifying that said processed food product contains 5% or less genetically modified crop material [after processing said harvested crop], based on said inspecting and testing.

New claims 52-61 have been added.